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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,183	01/18/2006	Paul Vermeij	I-2003.006 US	5236

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Intervet/Schering-Plough Animal Health
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EXAMINER	
DEVI, SARVAMANGALA J N	
ART UNIT	**PAPER NUMBER**
1645	

NOTIFICATION DATE	DELIVERY MODE
06/23/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/565,183	VERMEIJ, PAUL	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02/15/07*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 10-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-8 and 10-21* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Lack of Unity

1) Claim 9 has been canceled.

Claims 1-8 and 10-17 have been amended.

New claims 18-21 have added.

Claims 1-8 and 10-21 are under prosecution.

2) As provided in 37 CFR 1.475(a), a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFR 1.475(e).

3) As provided in 37 CFR 1.475(b), a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or

(2) A product and process of use of said product; or

(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process. Otherwise, unity of invention might not be present. See 37 CFR 1.475(c).

4) Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 C.F.R 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Claims 1-3, 10 and 14-17, drawn to a hybrid bacterial toxin subunit comprising an A1 part of Shiga or Shiga-like toxin fused to an A2 part of *E. coli* heat-labile enterotoxin, a vaccine comprising the same; a method for the preparation of the vaccine; and a method of combating *Shigella* or *E. coli* infection using the hybrid bacterial toxin subunit, classified in class 530, subclass 350.

II. Claims 4-8, 11, 12 and 19-21, drawn to a nucleic acid molecule encoding a hybrid bacterial toxin subunit comprising an A1 part of Shiga or Shiga-like toxin fused to an A2 part of *E. coli* heat-labile enterotoxin wherein the A1-part is optionally A1 of Stx2e, a DNA and a recombinant carrier comprising the same, and a vaccine comprising the same, classified in class 536, subclass 23.7.

III. Claim 13, drawn to a vaccine comprising antibodies against a hybrid bacterial toxin subunit comprising an A1 part of Shiga or Shiga-like toxin fused to an A2 part of *E. coli* heat-labile enterotoxin wherein the A1-part is optionally A1 of Stx2e, classified in class 514, subclass 8.

5) Inventions I-III lack unity. The special technical features of inventions I-III are delineated above. The hybrid bacterial toxin subunit is a protein comprising amino acid residues. The nucleic acid molecule of invention II comprises purine and pyrimidine units. The antibodies of inventions III are glycoproteins which include IgG that comprises 2 heavy and 2 light chains containing constant and variable regions, including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs) that function to bind an epitope. The antibody and the peptide epitope products are divergent with regard to their structure and/or function, each requiring separate and non-coextensive searches. The protein of invention I, the nucleic acid of invention II, and the antibodies of invention III do not share significant structural elements. Furthermore, these products require separate and non-coextensive searches.

6) This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1 because under PCT Rule 13.2, the species lack the same or corresponding special technical features as these species do not share a *significant* common structure, function and/or antigenic make-up.

(I) Additional antigen species: (a) Antigen from a virus pathogenic to humans; (b) Antigen from a virus pathogenic to animals; (c) Antigen from a microorganism pathogenic to humans; (d) Antigen from a microrogansim pathogenic to animals; (e) Antibody against an antigen from a virus pathogenic to humans; (f) Antibody against an antigen from a virus pathogenic to animals; (g) Antibody against an antigen from a microorganism pathogenic to humans; (h) Antibody against an antigen from a microorganism pathogenic to animals; (i) Genetic information encoding an antigen from a virus pathogenic to humans; (j) Genetic information encoding an antigen from a virus pathogenic to animals; (k) Genetic information encoding an antigen from a microorganism pathogenic to humans; (l) Genetic information encoding an antigen from a microorganism pathogenic to animals. See claim 14. Claims 1-3, 10 and 15 are generic.

(II) Virus or microorgansim species: (A) Pseudorabies virus; (B) Porcine influenza virus; (C) Porcine parvo virus; (D) Transmissible gastroenteritis virus; (E) Rotavirus; (F) *Brachyspira hyodysenteriae*; (G) *E. coli*; (H) *Erysipelothrix rhusiopathiae*; (I) *Bordetella bronchiseptica*; (J) *Shigella* sp.; (K) *Salmonella choleraesuis*; (L) *Salmonella typhimurium;* (M) *Salmonella enteritidis;* (N) *Haemophilus parasuis*; (O) *Pasteurella multocida*; (P) *Streptococcus suis*; (Q) *Mycoplasma hyopneumoniae*; (R) *Actinobacillus pleuropneumoniae*; (S) *Staphylococcus hyicus*; and (T) *Clostridium perfringens*. See claim 15. Claims 1-3, 10 and 14 are generic.

(III) Infection species: (1) *Shigella* infection; and *E. coli* infection. See claim 16.

7) Applicant is required under 35 U.S.C 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

8) The election of species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, Applicant must indicate which of these claims are readable on the elected species.

Should Applicants traverse on the ground that the species are not patentably distinct, Applicants should submit evidence or identify such evidence now of record, showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C § 103(a) of the other invention.

9) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Central Fax number, (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

10) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.Mov. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

11) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Robert Mondesi, can be reached on (571) 272-0956.

/S. Devi/
Primary Examiner
AU 1645

June, 2009